

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER 2006 - 021

37 CFR 1.5) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/IB2004/003872 24 November 2004 TITLE OF INVENTION Pharmaceutical compositions of Mirtazapine APPLICANT(S) FOR DO/EO/US Phanindrudu Aluri, Justin Babu, Shaik Srinivasa Rao, Ashish Gogia Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. X This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). x has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 10. Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording, A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

IAPS REC'OPCTIPTO 22 MAY 2006

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0851-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (# known, see 37 CER 15) INTERNATIONAL APPLICATION NO. PCT/IB2004/003872			ATTORNEY'S DOCKET NUMBER 2006-021		
20. Other items or information: Oath to be submitted later, surcharge already included in above fee computation.					
The following	fees have been submitted			CALCULATIONS	PTO USE ONLY
21. X Basic national fee (37 CFR 1.492(a))			\$ 300.00		
22. 🔀 Examination	on fee (37 CFR 1.492(c))				
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$ 200.00	
23. Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$ 400.00	
TOTAL OF 21, 22 and 23 =				900.00	
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets Extra Sheets Number of each additional 50 or fraction thereof (round up to a whole number)					
- 100 =	/50 =		x \$250	\$	1
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	23-20=	3	× \$ 50	\$ 150.00	
Independent claims	5 - 3 =		x \$200	\$ 400.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$380				\$	<u> </u>
TOTAL OF ABOVE CALCULATIONS =				\$ 680.00	
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 1,580.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +				\$	
TOTAL NATIONAL FEE =				\$ 1,580.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
TOTAL FEES ENCLOSED =				\$ 1,580.00	
				Amount to be refunded:	\$
				Amount to be charged	\$ 1,580.00

Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

a. A check in the amount of \$ __ to cover the above fees is enclosed. Please charge my Deposit Account No. _ in the amount of \$ ___ to cover the above fees. A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit ____. A duplicate copy of this sheet is enclosed. Account No. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. & Skears SEND ALL CORRESPONDENCE TO: Jay Akhave Jay Akhave #612, 2058 N Mills Ave NAME Claremont 50,016 CA 91711 REGISTRATION NUMBER May 22, 2006

10/580391 Page 1 of 1

EXPRESS MAIL LABEL NO: EQ 569289965 US

Commissioner for Patents POB 1450 Alexandria, VA 22313-1450 May 22, 2006

Re:

PCT Application No. PCT/IB2004/003872

Subject:

REQUEST ENTRY INTO U.S. NATIONAL STAGE

Sir:

We hereby request entry into U.S. national stage for this PCT application. An international search report has been issued on May 24, 2005 by the European Patent Office. This application has been published WO 2005/051349 A2 in English.

A preliminary amendment has been filed with this mailing. A surcharge fee for late oath submission has been included in the computation of submitted fees for this filing.

Items submitted with this mailing are:

PTO 1390, PTO 2038, Preliminary Amendment (4 pages)

Respectfully submitted,

Jay R Akhave Reg. No. 50,016

#612, 2058 N Mills Ave Claremont CA 91711 909 625 3761